UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

PORTAL INSTRUMENTS, INC.,

Plaintiff,

v.

LEO PHARMA A/S,

Defendant.

Case No. 22 Civ. 9156 (JHR)

REPLY IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

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Defendant LEO Pharma A/S ("LEO") respectfully submits this Reply in support of its Motion to Dismiss Count I of the Complaint filed by Portal Instruments, Inc. ("Portal").

PRELIMINARY STATEMENT

Portal's opposition seeks to avoid dismissal of its Development Fee claim by contorting the contract language to create an ambiguity that does not exist. Portal's arguments fail because the Agreement's plain language makes clear that, after LEO elected to cease development of the 1x2mL System in September 2021, it had "no obligation to make *any future installment payments* towards the 1x2mL System Development Fee," including the October 2021 installment payment Portal seeks to recover.

Portal's attempts to elide the clear meaning of this language are unavailing. Portal primarily argues that LEO's interpretation would render the separate 90-day notice period for terminating the contract a "nullity," but that is simply false. An election to cease development and a decision to terminate the contract are distinct, and the 90-day notice period for contract termination is not rendered a nullity by interpreting the Agreement in this manner; rather, the notice period continues to apply to numerous other obligations, including the obligation to make milestone payments (to the extent they become due during the notice period) as well as various contractual covenants. Nor is this interpretation of the contract commercially unreasonable, as Portal asserts. By entering into the Agreement, Portal assumed the risk that LEO would elect to cease development, ending its obligation to pay further Development Fees. In exchange, Portal received valuable consideration, including a \$12 million upfront payment and the \$10.5 million of installment payments made before development stopped. There is nothing unreasonable or unconscionable about this allocation of risk, especially when agreed to by sophisticated parties.

Portal's effort to create ambiguity fails for the additional reason it does not and cannot advance any reasonable alternative interpretation. Portal argues that the provision releasing LEO

of any obligation for "any future installment payments" should be limited to a subset of future payments that become due 90 days after a notice of termination of the contract, but there is no basis for such a limitation in the Agreement. Portal's theory is a blatant attempt to rewrite the Agreement, and its Development Fee claim should therefore be dismissed with prejudice.

ARGUMENT

I. The Agreement Unambiguously Releases LEO of Any Obligation to Pay Any Future Development Fee Installments After an Election to Cease Development.

Portal attempts to avoid the dismissal of its Development Fee claim by arguing that the Agreement is ambiguous, but Portal is wrong. "It is well settled that a contract is unambiguous if the language it uses has a definite and precise meaning, as to which there is no reasonable basis for a difference of opinion." *Lockheed Martin Corp. v. Retail Holdings*, 639 F.3d 63, 69 (2d Cir. 2011). The contract language at issue here is clear and unequivocal.

The contract provides that LEO may "at any point ... provide Portal with written notification to change its election, including to cease ... to Develop a System." Compl. Ex. A (ECF No. 30-1) ("Agreement") § 4.2 (emphasis added). It further states that, if "LEO Pharma elects to cease the Development of the 1x2mL System, then LEO Pharma shall have no obligation to make any future installment payments towards the 1x2mL System Development Fee." Id. § 7.2(a) (emphasis added). These provisions make clear that an election to cease development may be made "at any point," following which LEO shall have no obligation to make "any future installment payments." As used in the contract, the term "future" is not ambiguous. It means any later point in time following the election to cease development. See ECF 35 (MTD), 9. The plain meaning of "future," the unqualified reference to "any future installment payments," and Section 7.2(a) as a whole all make clear that this provision releases LEO of any obligation to pay any Development Fee payments that would otherwise be due after

LEO elects to cease development—not merely the subset of future payments due more than 90 days later or after the effective date of a notice of termination of the contract.

This interpretation is not only mandated by the plain language of the Agreement, but consistent with the contract's stated purpose for Development Fee payments—to provide "Development Funding." Agreement § 7.2; see also id. § 7.2(a) (providing that the Development Fee will be paid over the "1x2mL System Development Period"). It would make no sense to require LEO to provide "Development Funding" for a period after development had ceased, by for example, requiring LEO to make the October 2021 Development Fee payment Portal seeks to recover, which covers the calendar quarter after development stopped. See Compl. ¶ 29.

Portal does not dispute that the plain meaning of Section 7.2(a) supports LEO's interpretation. *See* Opp. (ECF No. 39), 13-18. Instead, Portal argues that LEO's interpretation would: (1) make the 90-day pre-termination notice provision surplusage, (2) be inconsistent with the Agreement's termination provision, and (3) create a commercially unreasonable or unconscionable result. *Id.* All three arguments are unpersuasive.

First, Portal is wrong that LEO's interpretation would make the 90-day termination notice provision meaningless. *See id.* at 11-13. To the contrary, in the event of a termination of the Agreement, the 90-day notice period still preserves numerous obligations. For example, LEO would still be required to make milestone payments, to the extent that a milestone event occurred during the 90-day notice period. *See* Agreement § 17.6. In addition, the covenant not to sue (§ 2.6), the covenant not to enter conflicting agreements (§ 12.5(a)), the covenant regarding assignment of inventions (§ 12.5(b)), and regulatory compliance provisions (§ 5.4), would all remain in effect during the 90 days following a notice of termination. In short, reading Section 7.2(a) to mean what it says—that LEO has no obligation to pay Development Fee installments

after an election to cease development—does not render the 90-day notice period for contract termination meaningless or superfluous. *See Montauk Oil Transp. Corp. v. Steamship Mut. Underwriting Ass'n (Bermuda) Ltd.*, 79 F.3d 295, 298 (2d Cir. 1996) ("[A] contractual provision is not rendered superfluous or ineffective simply because it may not apply to a particular case.").

Second, Portal argues that the 90-day termination notice requirement should apply to LEO's election to cease development because the election constitutes a termination with respect to a Product. See Opp. 13-16. Portal is wrong. The Agreement makes clear that electing to cease development of a System is different than terminating the Agreement with respect to a Product. Compare Agreement § 7.2, with id. § 17.2(a). Portal's attempt to conflate these two rights is inconsistent with the plain language and structure of the Agreement, which uses different terminology ("cease the Development of the ... System" vs. "terminate the Agreement ... on a Product-by-Product basis") in different sections (Section 7.2 vs. Section 17.2) to describe them. "The use of similar but different terms in a single contract strongly implies that the terms are to be accorded different meanings." Eastman Kodak Co. v. Altek Corp., 936 F. Supp. 2d 342, 355 (S.D.N.Y. 2013) (citation and internal quotation marks omitted).

Here, LEO's election to cease development clearly did not amount to a termination of the Agreement with respect to a "Product" for the reason that the system being developed by the parties was not yet a "Product" as defined in the Agreement. The definition of a "Product" is the combination of LEO's drug with a Device and/or Cartridge "developed in accordance with and pursuant to this Agreement"; it does not extend to Devices that remain under development. Agreement § 1.109 (emphasis added). Nor does the fact that the Agreement contemplates testing the constituent parts of a potential "Product" suggest that a "Product" can exist before such

testing is complete. An agreement to test the stability of a foundation during the construction of a building doesn't convert the foundation into a building before it has walls and a roof.

Notwithstanding Portal's argument, the definition of "Clinical Trial" in Section 1.29 of the Agreement also does not support Portal's claim that the parties had developed a "Product" because the definition refers only to the use of a Product in a "human clinical study or trial"

Id. § 1.29 (emphasis added). By the time human Clinical Trials are conducted, a Product would already exist—i.e., the parties would have combined a fully developed Device with LEO's Drug for testing on human subjects. Here, by contrast, the 1x2mL System was still under development when LEO elected to cease further development activities; there was no Product to test on human subjects. See Compl. ¶ 19; Opp. 15 (conceding that the 1x2mL System was still in development). The bioequivalence study alleged in the Complaint was a "study on animals," Compl. ¶ 42 (emphasis added), not humans. Accordingly, it was not a "Clinical Trial" of anything—let alone a completed Product.

Finally, Portal asserts that LEO's interpretation is commercially unreasonable because it allows LEO to cease development and avoid further payments without sufficient notice. Opp. 16-18. But there is nothing commercially unreasonable, let alone unconscionable, about allocating the risk to Portal of any wind down costs it incurs following LEO's election to cease development. LEO specifically bargained for language allowing it to cease development "at any point ... in its discretion." Agreement § 4.2 While the parties could have agreed that LEO should pay Portal's wind down and other costs in the event of such an election, they did not, and instead made clear in the Agreement that LEO had "no obligation to make any future installment payments" after electing to cease development. *Id.* § 7.2(a). In exchange for assuming this risk, Portal received valuable consideration, including a \$12 million non-refundable upfront payment,

the right to Development Fees while development work was ongoing, and the possibility of milestone payments. *See* MTD at 3. Having reaped the benefits of the Agreement in the form of a \$12 million upfront payment—and \$10.5 million in Development Fees paid while development was ongoing—Portal cannot fairly protest that it is unreasonable to enforce LEO's bargained-for contractual right to stop paying Development Fees as soon as it elected to cease development.

II. Portal's Alternative Interpretation of the Agreement Is Unreasonable.

Portal's attempt to create ambiguity should be rejected for the additional reason that it fails to advance any reasonable alternative interpretation. "[T]he language of a contract is not made ambiguous simply because the parties urge different interpretations." *Aetna Cas. & Sur. Co. v. Aniero Concrete Co.*, 404 F.3d 566, 598 (2d Cir. 2005) (quoting *Bethlehem Steel Co. v. Turner Constr. Co.*, 2 N.Y.2d 456, 459 (1957)). To demonstrate an ambiguity, Portal must show that the contract language "is capable of more than one meaning when viewed objectively by a reasonably intelligent person who has examined the context of the entire integrated agreement." *Lockheed*, 639 F.3d at 69. A party's interpretation that "strain[s] the contract language beyond its reasonable and ordinary meaning" does not create an ambiguity. *Aetna Cas.*, 404 F.3d at 598 (quoting *Bethlehem Steel*, 2 N.Y.2d at 459).

Portal's argument that the phrase "any future installment payments" is limited to the subset of future installment payments due after a 90-day notice period triggered by a separate notice to terminate the contract strains the contract language far beyond any reasonable reading. Portal fails to explain how its interpretation can possibly be squared with the Agreement's plain language, which releases LEO of any "obligation to make *any* future installment payments," without any hint of a notice requirement or any limitation on the future installment payments to which it applies. Agreement § 7.2(a). Nor does Portal explain how its interpretation is workable in a situation where LEO elects to cease development *without* terminating the Agreement,

creating the absurd possibility that LEO could be required to pay every single future

Development Fee installment even after it elects to cease development. *See* MTD 9-10.

Pretending these problems do not exist, Portal argues that its interpretation is reasonable because it purportedly "harmonizes" the provision releasing LEO from the obligation to make future installment payments after an election to cease development with the Agreement's separate termination provision. Opp. 7. But there is no need to rewrite the plain language of the Agreement to "harmonize" two provisions that are already consistent. As explained above, the right to cease development and the right to terminate operate independently under separate provisions of the Agreement. There is no conflict between them in need of harmonizing. Further, Portal's interpretation does not actually "harmonize" these provisions. Instead, it grafts a non-existent advance notice requirement onto LEO's right to cease development. While the parties could have written the Agreement to require advance notice before an election to cease development became effective, they chose not to do so. Portal should not be permitted to rewrite the parties' contract by smuggling in a notice requirement from a distinct provision of the Agreement. See Vermont Teddy Bear Co. v. 538 Madison Realty Co., 1 N.Y.3d 470, 475 (2004) ("[C]ourts may not by construction add or excise terms, nor distort the meaning of those used and thereby make a new contract for the parties under the guise of interpreting the writing.").

Portal also argues that its interpretation is reasonable because (in its view) no language in the contract specifically exempts an election to cease development from the 90-day notice requirement for contract termination. Opp. 9. The argument is nonsensical because there is no advance notice requirement that applies to an election to cease development. The contract provides that such an election may be made "at *any* point" (Agreement § 4.2), following which LEO shall have no "obligation to make any future installment payments" (*id.* § 7.2(a)). The fact

that the parties did not add language excluding future Development Fee payments from the 90-day notice period governing contract termination is unsurprising since that provision governs only contract termination—not an election to cease development of a System, which would not necessarily result in a termination of the contract.

Finally, Portal argues its interpretation is "reasonable when considering the intention of the parties and the reasoning behind notice provisions." Opp. 9. But courts must "give effect to the intention of the parties as expressed in the unequivocal language they have employed."

Cruden v. Bank of New York, 957 F.2d 961, 976 (2d Cir. 1992) (emphasis added). Here, that unequivocal language released LEO of the "obligation to make any future installment payments" following an election to cease development, without imposing any prior notice requirement.\(^1\)

Agreement \(^8\) 7.2(a). Portal may wish the Agreement read differently, but the Court is not free to rewrite the plain language of the contract simply because Portal now believes that it is unreasonable or inequitable. Under New York law, courts do not "rewrite the plain language of [contracts] negotiated between sophisticated business entities." Cellular Tel. Co. v. 210 E. 86th St. Corp., 44 A.D.3d 77, 83 (1st Dep't 2007). Instead, "Courts will give effect to the contract's language and the parties must live with the consequences of their agreement." Eujoy Realty Corp. v. Van Wagner Commc'ns, LLC, 22 N.Y.3d 413, 424 (2013).

CONCLUSION

For the foregoing reasons, LEO's Motion to Dismiss Count I should be granted.

¹ Portal also asserts that its interpretation reflects "industry practice." Opp. 2. "But New York law is well settled that ... industry practice may not be used to vary the terms of [a complete and unambiguous] contract," such as the Agreement here. *Keiler v. Harlequin Enterprises Ltd.*, 751 F.3d 64, 69 (2d Cir. 2014). And even where ambiguity exists, to be relevant, industry custom or practice must be "general, uniform and unvarying," *Belasco Theatre Corp. v. Jelin Prods., Inc.*, 270 A.D. 202, 206 (1st Dep't 1945), and both parties must "kn[o]w or ha[ve] reason to know of it," *Starr Indem. & Liab. Co. v. Brightstar Corp.*, 388 F. Supp. 3d 304, 332 (S.D.N.Y. 2019). Portal does not even attempt to argue that these requirements are satisfied.

New York, New York Dated: February 10, 2023 Respectfully submitted,

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